ISO 9001:2000 Gap Analysis

This gap analysis is a synopsis of ISO 9001:2000 requirements and does not include exact text from the standard. It should not be used in lieu of the ISO 9001:2000 standard for implementation purposes, but as an evaluation tool to determine major system gaps. Further review of the ISO standard will be required to identify specific gaps.

Shall	Yes/No/Partial
General Requirements	
Has a quality management system (QMS) been established, documented, implemented, and maintained according to the ISO 9001 standard?	
Have criteria and methods needed been identified to ensure that both the operation and control of the processes needed for the QMS are effective?	
Are processes monitored, measured, analysed, and managed in accordance with the requirements of this International Standard?	
Are outsourced activities that affect product conformity identified and controlled within the QMS?	
Does the QMS include: - a quality policy and quality objectives - documented procedures required by the ISO Standard - documents needed to ensure the effective planning, operation and control of its processes, and - quality records required by the ISO 9001 standard?	
Documentation and Records	
Does the organization have a Quality Manual?	
Does the QM identify the scope of application of the QMS?	
Does the QM identify or provide links to the documented procedures established for the QMS?	
Does the QM identify processes, along with their sequence and interaction, needed for the QMS?	
Are the controls for document systems needed by the QMS documented in a procedure?	
Does the procedure include: approval/re-approval, changes are identified, relevant versions are available, documents remain legible and readily identifiable, controls for external documents, and to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose?	
Are quality records established and maintained?	
Are quality records legible, readily identifiable and retrievable?	
Has a documented procedure been established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of quality records?	
Customers	
Doe top management ensure that customer requirements are met with the aim of enhancing customer satisfaction? Is this information monitored?	
Does the organization communicate with customers in relation to product information, inquiries, contracts or order handling, including amendments, and customer feedback, including customer complaints?	

Quality policy	

Has top management established a quality policy that is
      - appropriate to the purpose of the organization?
      - Does the Quality Policy include a commitment to comply with requirements
      - and continually improve the effectiveness of the QMS?
      - a framework for establishing and reviewing quality objectives?
      - communicated and understood within the organization?
      - reviewed for continuing suitability?	

Quality objectives	
Has top management established quality objectives that are measurable and consistent with the quality policy? Does top management ensure that its personnel are aware of the objectives and know how they contribute to the achievement of the quality objectives?	
Quality management system planning	
Does top management plan and make changes by taking into consideration the processes of the QMS and the quality objectives?	
Responsibility and authority	
Has top management defined and communicated responsibilities and authorities?	
Management representative	

Has top management appointed a member of management to serve as management representative with responsibilities including
      - ensuring that processes needed for the QMS are established, implemented and maintained,
      - reporting to top management on the performance of the QMS, and
      - promoting awareness of customer requirements?	

Internal communication	
Has top management ensured that appropriate communication is provided regarding the QMS as well as meeting customer, statutory, and regulatory requirements?	
Management Review	
Does top management review the QMS at planned intervals to ensure its continuing suitability, adequacy and effectiveness?	
Are inputs (audit results, customer feedback, process performance and product conformity, status of preventive and corrective actions, follow-up actions from previous management reviews, planned changes that could affect the QMS) and outputs (improvement of the effectiveness of the QMS and its processes, improvement of product related to customer requirements, and resource needs) identified?	
Are records maintained of the reviews?	
Resources	
Has the organization determined and provided the resources needed to implement and maintain the QMS and to enhance customer satisfaction?	
Competence, awareness, and training	
Has the organization determined the necessary competence for personnel performing work affecting product quality and provided training or taken other action to satisfy these needs?	
Is training evaluated for its effectiveness?	
Are records of education, training, skills and experience maintained?	
Infrastructure	
Does the organization determine, provide and maintain for the infrastructure (buildings, workspace and associated utilities, process equipment, both hardware and software, and supporting services such as transport or communication) needed to achieve conformity to product requirements?	
Work environment	
Has the organization determined the work environment needed to achieve conformity to product requirements?	

Planning or product realization	
Has the organization planned and developed the processes needed for product realization in a form suitable for the organization's method of operations.?	
In planning product realization, are the following determined, as appropriate, quality objectives and requirements for the product; the need to establish processes, documents, and provide resources specific to the product; required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance; required records?	
Determination of requirements related to the product	
Does the organization determine requirements specified by the customer, including the requirements for delivery and post-delivery activities, requirements not stated by the customer but necessary for specified use or known and intended use, statutory and regulatory requirements related to the product?	
Review of requirements related to the product	
Does the organization review requirements related to the product prior to the organization's commitment to the customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders)?	
Are product requirements are defined, contract or order requirements differing from those previously expressed are resolved, and an evaluation made to the organization has the ability to meet the defined requirements?	
Are records maintained of these actions?	
Are verbal commitments confirmed by the organization before acceptance?	
Are relevant documents amended and relevant personnel notified when changes are made?	
Design and development	
Does the organization plan and control the design and development of product?	
During the design and development planning, are the design and development stages, who is responsible, and the appropriate review, verification and validation that are appropriate to each design and development stage determined?	
Is verification performed to ensure that outputs have satisfied the design and development input requirements?	
Does the organization manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility?	
Is planning output updated, as appropriate, as the design and development progresses?	
Are records for design and development, including inputs; results of design reviews, verification, validation, and the review of changes maintained?	
Do inputs include: - functional and performance requirements, - applicable statutory and regulatory requirements, - where applicable, information derived from previous similar designs, and - other requirements essential for design and development.	
Are inputs reviewed for adequacy to ensure they are complete, unambiguous and not in conflict with each other?	
Are the outputs of design and development provided in a form that enables verification against the input and is this approved prior to release?	
Do outputs meet the input requirements for design and development, provide appropriate information for purchasing, production and for service provision, contain or reference product acceptance criteria, and specify the characteristics of the product that are essential for its safe and proper use.	
Are systematic reviews of design and development conducted to evaluate the ability of the results of design and development to fulfil requirements, and to identify any problems and propose necessary actions?	

Question	
Do reviews include representatives of functions concerned with the design and development stage(s) being reviewed?	
Is validation performed in accordance with planned arrangements to ensure that the resulting product is capable of fulfilling the requirements for the specified or known intended use or application?	
Wherever practicable, is validation completed prior to the delivery or implementation of the product?	
Are the changes reviewed, verified and validated, as appropriate, and approved before implementation? Does the review include evaluation of the effect of the changes on constituent parts and delivered product?	
Purchasing process	
Does the organization ensure that purchased product conforms to specified purchase requirements? Does the organization apply the type and extent of control to the supplier and the purchased product dependent upon the effect of the purchased product on subsequent product realization or the final product?	
Has criteria for selection, evaluation, and re-evaluation of suppliers been established? Are suppliers evaluated and selected based on their ability to supply product in accordance with the organization's requirements?	
Are records of supplier evaluations maintained?	
Purchasing information	
Does purchasing information describe the product to be purchased, including where appropriate requirements for approval of product, procedures, processes and equipment, requirements for qualification of personnel, and quality management system requirements?	
Are specified purchase requirements reviewed for adequacy prior to their communication to the supplier?	
Verification of purchased product	
Has the organization established and implemented the inspection or other activities necessary for ensuring that purchased product meets specified requirements?	
When verification is performed at the supplier's premises, are the verification arrangements and method of product release included in the purchasing information?	
Control of production and service provision	
Is production and service provision planned and carried out under controlled conditions?	
Do controlled conditions include, as applicable, the availability of information that describes the characteristics of the product, the availability of work instructions, the use of suitable equipment, the availability and use of monitoring and measuring devices, the implementation of monitoring and measurement, and the implementation of release, delivery and post-delivery activities?	
Validation of processes for production and service provision	
Does the organization validate any processes, including those where deficiencies become apparent only after the product is in use or the service has been delivered, for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement? Does validation demonstrate the ability of these processes to achieve planned results?	
Does the organization have arrangements for these processes including, as applicable defined criteria for review and approval of the processes, approval of equipment and qualification of personnel, use of specific methods and procedures, records, and revalidation?	
Identification and traceability	
Is product, where appropriate, identified by suitable means throughout product realization?	
Is the product status with respect to monitoring and measurement requirements identified?	

Are records maintained, where required, to control and record the unique identification of the product?	
Customer property	
Is care exercised with customer property while it is under the control or being used by the organization, including identification, verification, protection and safeguarding?	
Is customer property that is lost, damaged or otherwise found to be unsuitable for use, reported to the customer and records maintained?	
Preservation of product	
Does the organization preserve the conformity of product and its constituent parts during internal processing and delivery (including identification, handling, packaging, storage and protection) to the intended destination?	
Control of monitoring and measuring devices	
Has the organization determine the monitoring and measurement and the devices needed to provide evidence of conformity of product to determined requirements?	
Have processes been established to ensure that monitoring and measurement can be carried out in a manner that is consistent with the requirements?	
Does the organization ensure that equipment is: a) calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification is recorded; b) adjusted or re-adjusted as necessary; c) identified to enable the calibration status to be determined; d) safeguarded from adjustments that would invalidate the measurement result; e) protected from damage and deterioration during handling, maintenance and storage?	
When equipment is found not to conform to requirements, does the organization assess the validity of previous measuring results and take appropriate action on the equipment and any product affected?	
Are records maintained?	
Is computer software used in the monitoring and measurement of specified requirements that is used to satisfy the intended application confirmed.When, the ability of	
Monitoring, Measurement, and Analysis	
Have monitoring, measurement, analysis and improvement processes been implemented to demonstrate conformity of the product, to ensure conformity of the QMS, and to continually improve the effectiveness of the QMS?	
Does the organization determine applicable methods, including statistical techniques, and the extent of their use?	
Internal audit	
Are internal audits conducted at planned intervals? Do audits review the QMS to planned arrangements, the ISO standard, and to established QMS requirements? Do audits determine whether the QMS is effectively implemented and maintained?	
Does the audit program take into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits? Are the audit criteria, scope, frequency and methods be defined?	
Are auditors selected to ensure objectivity and impartiality? Are actions in place to ensure auditors do not audit their own work?	
Are responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records defined in a documented procedure?	
Monitoring and measurement of processes	
Does the management responsible for the area being audited ensure that timely action is taken to eliminate detected nonconformities and their causes? Are follow-up activities verified?	

Does the organization apply suitable methods for monitoring and, where applicable, measurement of the QMS processes to demonstrate the ability of the processes to achieve planned results?	
When planned results are not achieved, is correction and corrective action taken, as appropriate, to ensure conformity of the product?	
Monitoring and measurement of product	
Does the organization monitor and measure the characteristics of the product to verify that product requirements are fulfilled at appropriate stages of the product realization process in accordance with the planned arrangements?	
Is evidence of conformity with the acceptance criteria maintained, including records indicating the person(s) authorizing release of product?	
Is product release and service delivery delayed until all the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority, and where applicable by the customer?	
Control of nonconforming product	
Does the organization ensure that product which does not conform to requirements is identified and controlled to prevent its unintended use or delivery? Are the controls and related responsibilities and authorities defined in a documented procedure?	
Does the organization deal with nonconforming product by one or more of the following ways: by taking action to eliminate the detected nonconformity; by authorizing its use, release or acceptance under concession by a relevant authority; by taking action to preclude its original intended use or application?	
Are records, including concessions obtained, maintained?	
Is nonconforming product that has been corrected subject to re-verification to demonstrate conformity to the requirements?	
If nonconforming product is detected after delivery or use has started, is action taken appropriate to the effects, or potential effects, of the nonconformity?	
Analysis of data	
Does the organization determine, collect, and analyze appropriate data (customer satisfaction, conformance to product requirements, trends of processes and products, including opportunities for preventive action, suppliers) to demonstrate the effectiveness of the QMS?	
Continual improvement	
Are actions implemented to achieve planned results and continual improvement of these processes? Does the organization continually improve the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review?	
Corrective and Preventive action	
Does the organization have a system to eliminate the cause of nonconformities in order to prevent recurrence and occurrence?	
Are these systems documented in a procedure?	
Does the system include customer complaints?	
Are actions identified, implemented, and reviewed?	
Are records of results of actions taken maintained?	